

REMARKS

Claim 1 has been amended to require the presence of 0.1 to 10% adenosine compound. Support for this amendment exists, *inter alia*, at page 8, line and page 18, line 1. Claims 4-6, 13-15 and 23 have been amended accordingly.

Claims 1-6, 8-15 and 17-23 are currently pending.

The Office Action rejected claims 1, 8, 21 and 22 under 35 U.S.C. § 102 as anticipated by U.S. patent 6,423,327 ("Dobson"), claims 1 and 2 under 35 U.S.C. § 102 as anticipated by U.S. patent 3,978,213 ("Lapinet"), and claims 2-6, 9-15, 17-20 and 23 under 35 U.S.C. § 103 as obvious over Dobson. In view of the following comments, Applicant respectfully requests reconsideration and withdrawal of these rejections.

The pending claims relate to methods of softening expression lines using specified amounts (0.1-10%, more specifically 0.1-1.0%) of an adenosine compound. Of particular note, the invention methods require direct application of the specified amount of the adenosine compound to the expression lines with the intent and effect of softening the expression lines. None of the applied art teaches or suggests these unique treatment methods.

Dobson teaches applying minimal, millimolar amounts of adenosine such that dermal cell proliferation is avoided. Thus, the express teaching of Dobson is to strictly limit the amount of adenosine used to achieve a desired effect while, importantly, avoiding an undesired effect resulting from the use of too much adenosine. In other words, Dobson expressly teaches away from using "significant" (that is, greater than 10^{-3} M) amounts of adenosine. This is in sharp contrast to the claimed invention which requires the presence of a significant amount of adenosine compound to achieve the required dermo-relaxation effect.

One skilled in the art, following Dobson, would be led to use extremely minimal amounts of adenosine and, thus, would be led away from the presently claimed invention which requires application of significant amounts of adenosine compound to effect dermo-relaxation. Given this fundamental teaching away by Dobson, Dobson cannot teach or suggest the claimed invention.

Regarding Lapinet, this reference teaches that an adenosine derivative is effective at “soothing and softening skin.” (Col. 1, lines 50-53). Lapinet exemplifies providing the neck area with a more youthful appearance. (Col. 4, lines 1-5). Significantly, despite applying his compositions to the face, Lapinet does not report that his compositions are effective on the face. Thus, the question is whether Lapinet’s teaching regarding using a adenosine compound to smooth skin on the neck would lead one skilled in the art to practice the claimed invention which requires dermo-relaxation of the face and/or forehead in need of such relaxation.

The CAFC’s decision in *Jansen v. Rexall Sundown Inc.*, 68 U.S.P.Q.2d 1154 (Fed. Cir. 2003) provides guidance regarding how to answer this question. In *Jansen*, the CAFC provides specific guidance concerning how the pending claims are to be interpreted. This guidance resolves the prior art issue in this case and requires that the currently pending prior art rejections be withdrawn.

In *Jansen*, the claims were directed to methods of treating or preventing macrocytic-megaloblastic anemia comprising administering effective amounts of folic acid and vitamin B₁₂ to humans in need thereof. *Jansen* at 1157. In interpreting these claims, the Federal Circuit ruled that the claims require the specific intent to achieve the claimed objective

(treatment or prevention of macrocytic-megaloblastic anemia). Specifically, the Federal Circuit stated that:

. . . the claim preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone ‘in need.’ In both cases, the claims’ recitation of a patient or a human ‘in need’ gives life and meaning to preambles. [Citation omitted]. The preamble is therefore not merely a statement of effect that may or may not be desired or appreciated. Rather, **it is a statement of the intentional purpose for which the method must be performed.** We need not decide whether we would reach the same conclusion if either of the ‘treating or preventing’ phrase or the ‘to a human in need thereof’ phrase was not a part of the claim; **together, however, they compel the claim construction arrived at by both the district court and this court.**

Jansen at 1158 (emphasis added). The Federal Circuit further explained that:

the ‘083 patent claims are properly interpreted to mean that the combination of folic acid and vitamin B₁₂ **must** be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia.

Jansen at 1158 (emphasis added).

Thus, according to the Federal Circuit, claims directed to methods of treatment to be performed on those in need of such treatment require the specific intent to effect such treatment.

In the present application, the pending claims are directed to methods of softening expression lines on a face and/or forehead in need thereof by applying an effective amount of

adenosine compound to specific areas of skin in need of such softening. In accordance with the Federal Circuit's decision in *Jansen*, these claims must be interpreted to require the specific intent to effect softening of expression lines.

Lapinet neither teaches nor suggests such specific intent: that is, Lapinet does not state that the claimed adenosine compounds could or should be used to soften expression lines. In view of this fatal deficiency, Lapinet cannot teach or suggest the claimed methods.

This is particularly true for claims like claims 8, 9, 17, 18 and 23 which are specifically directed to adenosine. Lapinet does not teach or suggest applying adenosine to skin and, thus, cannot teach or suggest the subject matter of these claims.

Furthermore, the pending rejections are improper because in making the pending rejections, the Office Action asserted that because expression lines are a type of wrinkle and because Dobson and Lapinet relate to treating wrinkles, Dobson and Lapinet therefore relate to treating expression lines. However, the logic upon which this assertion is based is flawed, meaning that the rejections themselves are flawed.

As demonstrated by Exhibits A-C relied upon by the Office Action, expression lines differ from other wrinkles such as those caused by sun damage, and expression lines are "difficult to treat." Thus, merely because a reference might disclose methods of treating other types of less difficult-to-treat wrinkles, it does not mean that such a reference (directed to a different type of wrinkle) teaches or suggests anything about how to treat expression lines. In other words, for example, a disclosure related to treating wrinkles caused by sun damage cannot teach or suggest how to treat expression lines, which are recognized as being different, more difficult-to-treat types of wrinkles.

By way of analogy, baldness can be caused by different mechanisms such as, for example, alopecia or testosterone-related baldness. However, whereas testosterone-related baldness might be treatable using compounds which inhibit testosterone production or inhibit conversion of testosterone to active forms, alopecia cannot be treated using such compounds. Thus, although the effect (baldness) is the same, treatment methods are not interchangeable for the different types of baldness.

Similarly, in this case, treatment methods for treating one type of wrinkle are not interchangeable with methods for treating expression lines. Accordingly, references directed to treating wrinkles other than expression lines cannot teach or suggest methods of how to treat expression lines.

Neither Dobson nor Lapinet teaches or suggests softening expression lines by applying an adenosine compound thereto. Both Dobson and Lapinet teach treating wrinkles or damaged skin caused by sun, age and/or environmental factors such as wind. (See, Dobson at col. 1, lines 28-34 and Lapinet at col. 1, lines 49-56). As explained in the present specification (pages 2-4), the conditions treated by Dobson and Lapinet are different from expression lines: their causes are different and their treatments are different. For example, whereas wrinkles are caused by lack of collagen and can be addressed through collagen protection and/or synthesis, expression lines are caused by different mechanisms and cannot be addressed by increasing or protecting collagen. Thus, although Dobson and Lapinet teach addressing collagen-related conditions such as wrinkles or moisture-related conditions such as dry skin, these references neither teach nor suggest reducing or softening conditions unrelated to collagen or moisturization levels. Because expression lines are not collagen- or

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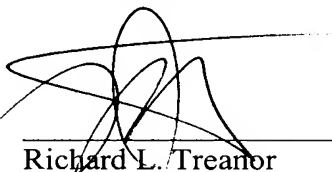
moisturization-related, neither Dobson nor Lapinet could possibly teach or suggest anything concerning treatment of this condition.

In view of the above, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 102 and 103.

Applicant believes that the present application is in condition for allowance. Prompt and favorable consideration is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Richard L. Treanor', is written over a horizontal line.

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